K070899

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Healthcare

Nellcor
Puritan Bennett

4280 Hacienda Drive
Pleasanton, CA 94588-2719

Tele: 925 463-4300
Fax: 925 463-4020

510(k) Summary

Submitted by:	Nellcor Puritan Bennett 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	James Bonds Senior Director Regulatory Affairs (925) 463-4371 Fax (925) 463-4020
Date Summary Prepared:	March 30, 2007
Trade Name:	Puritan Bennett Legendair XL2
Common/Usual Name:	Continuous Ventilator
Classification Name:	Ventilator (CBK) per 21 CFR §868.5895
Substantially Equivalent Devices:	TBird Legacy (K003770) and Pulmonetic Systems LTV 1000 (K051767)

DEC 1 3 2007

DEVICE DESCRIPTION

The LEGENDAIR® XL2 ventilator is composed of an airflow generator capable of supplying a range of flow rates and pressures and a valve enabling piloting of the expiration valve. The operation of the device is based on a self-adapting drive system governed by a closed loop flow generator. The speed of the flow generator (turbine) is servo-controlled to the patient pressure signal or the inspired flow signal.

The ventilation modes available are:

- Pressure Support Ventilation
- Pressure Support Ventilation with Back Up Rate
- CPAP mode

- Pressure Controlled Ventilation
- Pressure Assisted Controlled Ventilation
- Volume Controlled Ventilation
- Volume Assisted Controlled Ventilation
- Synchronous Intermittent Mandatory Ventilation with either volume or pressure targeted mandatory breaths

INTENDED USE

The Legendair XL2 is intended to provide continuous or intermittent mechanical ventilatory support as prescribed for patients weighing at least 5kg. The ventilator provides assist/control, SIMV, and CPAP modes of ventilation, and is intended for use in institutional, home, or transport settings. The Legendair XL2 is not intended for use as an emergency transport ventilator.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The performance is the Legendair XL2 is equivalent to the Bird Products Corporation TBird Vela Ventilator (K032451). Equivalence has been shown through a detailed comparison of performance modes, ranges of operation, and compliance with external electrical and mechanical safety standards. The results of these comparisons have demonstrated that the Legendair XL2 is safe and effective and performs equivalently to the TBird Legacy Ventilator and the Pulmonetic Systems LTV 1000 Ventilator

CONCLUSIONS

The technological characteristics of the Legendair XL2 ventilator and the results of testing do not raise new questions of safety or effectiveness when compared to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

Mr. James Bonds
Senior Director Regulatory Affairs
Nellcor Puritan Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, California 94588

Re: K070899
Trade/Device Name: Puritan Bennett Legendair XL2 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: November 30, 2007
Received: December 6, 2007

Dear Mr. Bonds

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:

Device Name: Puritan Bennett Legendair XL2 Ventilator

Indications for Use

The Legendair XL2 is indicated for the continuous or intermittent mechanical ventilatory support of patients weighing at least 5 kg who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients who require the following general types of ventilatory support, as prescribed by an attending physician:

- Positive Pressure ventilation
- Assist/Control, SIMV, or CPAP modes of ventilation
- Breath types including Volume, Pressure Control and Pressure Support.

The ventilator is suitable for use in institutional, home, and transport settings. It is not intended for use as an emergency transport ventilator.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070895

Prescription Use ___X___ AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)